

K050461

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JUL 27 2005

**510(k) Summary of Safety and Effectiveness:  
Xia® 4.5 Spinal System**

Proprietary Name: Xia® 4.5 Spinal System

Common Name: Spinal Fixation Appliances

Proposed Regulatory Class: Class II  
Spinal Interlaminar Fixation Orthosis, 21 CFR 888.3050  
Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060  
Pedicle Screw Spinal System, 21 CFR 888.3070

Device Product Code: 87 KWP: Appliance, Fixation, Spinal Interlaminar  
87 KWQ: Appliance, Fixation, Spinal, Intervertebral Body  
87 MNH: Spondylolisthesis Spinal Fixation System  
87 MNI: Orthosis, Spinal, Pedicle Fixation

For Information contact: Simona Voic  
Regulatory Affairs Project Manager  
2 Pearl Court  
Allendale, NJ 07401  
Telephone: (201) 760-8145  
Fax: (201) 760-8345  
Email: [Simona.Voic@stryker.com](mailto:Simona.Voic@stryker.com)

Date Summary Prepared: July 1, 2005

**Device Description**

The Stryker Spine Xia® 4.5 Spinal System offers a comprehensive solution for immobilizing and stabilizing spinal deformities in patients, particularly those with a smaller stature, as an adjunct to fusion. The Stryker Spine Xia® 4.5 Spinal System is comprised of Ø 4.5 mm rods, Polyaxial and Monoaxial screws, Blockers, Hooks, Dual Staples, and Connectors. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy. The implants will be provided non-sterile and will be used for either posterior or anterolateral non cervical fixation.

**Predicate Device Identification**

The Xia® 4.5 Spinal System is substantially equivalent to Stryker Spine Xia Spinal System (K002858), DePuy Spine MOSS Miami™ Spinal System (K950697 and K962628) and Medtronic Sofamor Danek CD Horizon Legacy™ (K020709).

**Intended Use:**

The XIA<sup>®</sup> 4.5 Spinal System is intended for posterior noncervical pedicle fixation for the following indications: severe spondylolisthesis (i.e. Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

The XIA<sup>®</sup> 4.5 Spinal System is also intended for anterolateral and posterior, non-cervical, non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

**Statement of Technological Comparison:**

The subject components share the same intended use and basic design concepts as that of the predicate device. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.



JUL 27 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms Simona Voic  
Regulatory Affairs Project Manager  
Stryker Spine  
2 Pearl Court  
Allendale, New Jersey 07401

Re: K050461

Trade/Device Name: Xia<sup>®</sup> 4.5 Spinal System  
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070  
Regulation Name: Spinal interlaminar fixation orthosis, Spinal intervertebral body  
fixation orthosis, Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNH, MNI, KWP, KWQ  
Dated: July 1, 2005  
Received: July 5, 2005

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

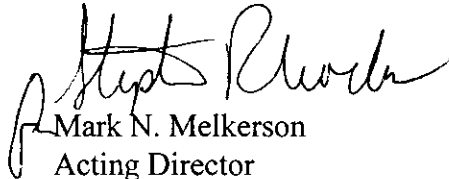
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K050461

Device Name: Xia® 4.5 Spinal System

### Indications For Use:

The XIA® 4.5 Spinal System is intended for posterior noncervical pedicle fixation for the following indications: severe spondylolisthesis (i.e. Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K050461